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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,099	07/26/2001	Charlotte Moira Norfor Allerton	PC22001AJTJ	8424

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,099

Applicant(s)

ALLERTON ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,5. 6) ☐ Other: ____

DETAILED ACTION

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 (part), drawn to Processes using (II), classified in class 544, subclass 262.
- II. Claims 1-3(part), drawn to Processes using (III, IV or V), classified in class 544, subclass 262.
- III. Claims 4-8, drawn to Acetylation of Pyridines, classified in class 546, subclass 299.

Claims 1-3 link inventions I and II. These claims are examined to the extent that they read on the elected invention.

The inventions are distinct, each from the other because of the following reasons: Each is drawn to a different type of reaction. Group II has cyclization which is not seen in either of the other two groups. Group III has an acetylation step not seen in the other groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with James Jones on 2/8/02 a provisional election was made without traverse to prosecute the invention of Group II, claims 1-3 in part. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-3 are rejected as being drawn to an improper Markush Group. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction. This does not constitute an art recognized genus. The claims are examined only to the extent that they read on the elected invention. Cancellation of the starting material choice (II) subject matter will overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bunnage.

The reference teaches the cyclization using potassium t-butoxide. The process is taught generically in the full paragraph in column 6. Solvents include ethers (examples 4, 25) and assorted alcohols (e.g. examples 8, 20, 21, 26, 43, 157 and others). The reaction is sometimes done with exchange of the group at the 2 position on the pyridyl, as in e.g. examples 25, 41, etc. The claim calls for a “hydroxide trapping agent”. As is noted below, the scope of this is unknown, but could well include both alcohols and

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ethers. OH for example will to some degrees exchange with alcohols. The recitation of "butanol" in claim 3 strengthens the notion that alcohols are intended.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25 of copending Application No. 09/684228. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same process is involved.

The issues are as indicated above. This application, which it is noted has a common priority document UK 0018660.1, discloses the use of alcohols in the process; see page 18.

Claims 1 and 3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 09/684853. The same process is involved, including the "hydroxide trapping agent" language. The only difference seems to be that the present case has a somewhat broader scope.

These are both provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. "Prodrug thereof" is indefinite. Determining whether a given derivative definitely is or is not a prodrug involves more than routine experimentation. If the derivative is active, open-ended experimentation may be involved to determine for sure whether the compound is a prodrug or whether it is active in its own right.
2. Further, the step of converting something to its prodrug form isn't present in the process. Note that the starting material isn't in the prodrug form.
3. At page 62, line 14, what does the "and/or terminated" add to the claim? That is, what is in "terminated" that is not already included in "substituted"? Likewise elsewhere where the term appears.
4. "Substituted" --- with what (page 64, line 13)?

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5. The ring at the last two lines of page 63 is unclear. Other than the N which forms the atom of attachment, what else is in the ring?
6. The last choice on page 62 is unclear. Is this $-S(O)R^{18}$ or $-S-O-R^{18}$?
7. The term "hydroxide trapping agent" is indefinite. This is not a standard term of art, and hence one of ordinary skill in the art does not know what it embraces. The specification says that it is preferably an ester, which implies that it covers more than that, but what?
8. What is, at page 64 line 19, an "auxiliary base"? Is it auxiliary to something else, and if so, what? How does this differ from a regular base?
9. That material in parenthesis at page 64 line 20 is vague. The "i.e." means that it is rewording something, but what? Whatever it might be, that material is being expressed twice, which is improper alternative language. In addition, the phrase itself is unclear. Does "is substituted by" mean that there has been a substitution reaction? Or does it mean that one is a substituent on the other?
10. Claim 2 lacks a definition for R^3 .
11. If $^-OR^3$ is actually the anion OR^{3-} , then it must be written correctly, with the charge at the right, not left side. If it is not, if the raised dash at the left is actually a bond, then it is a bond to what?
12. Claim 3 appears to be improperly dependent on claim 2. The potassium carbonate appears to provide the $^-OR^3$ but that would require that R^3 be $C(O)OK$, and even using the claim 1 definition for R^3 , $COOK$ is not embraced.
13. The term "in the case of the formation of compound (IA)" in claim 2 makes no sense. This compounds (IA) is always formed. The claim *is* the preparation of (IA).

Claims 1-2 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

If OR^3 is actually the anion OR^{3-} , then this is problematic. One cannot have free anions. It must be in the presence of an actual molecule, e.g. potassium t-butoxide, so that this is impossible (paragraph 1). Alternatively if applicants do not actually intend to claim something impossible, then the claim is not accurate, as it recites a free anion when applicants really intend a molecule.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

See point 11 above. This choice for R3 isn't even in the specification definition's of R3, and hence such a process does not fall within the generic description of the invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most other cases, does not reasonably provide enablement for $Q = \text{NR}^5$ when III or IV is used. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The process as written has no step to introduce the NR⁵ group. Unless it is already present, which is the case for starting material V, the process does not make such a compound.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most R⁴ choices does not reasonably provide enablement for when R⁴ has OR⁶, halo, halo-alkyl, -SOR¹⁸ or OC(O)R⁷. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

This process operates by the displacement of the substituent X on the pyridine ring, which is a leaving group. The above mentioned groups are themselves leaving groups; see page 11. Therefore, these groups will themselves be displaced.

Specification

The abstract is objected to. Structures are needed. The issues above listed as points 6-8 apply to the abstract as well.


The sentence at page 1, lines 15-16 is objected to as incorrect. Example 132 is not a cyclization, but just a displacement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

February 20, 2002